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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/639,617	08/12/2003	James E. Darnell JR.	600-1-073CIPCON	5404

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KLAUBER & JACKSON
411 HACKENSACK AVENUE
HACKENSACK, NJ 07601

EXAMINER	
WAX, ROBERT A	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 05/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/639,617	DARNELL ET AL.	
	Examiner	Art Unit	
	Robert A. Wax	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-68* is/are pending in the application.

4a) Of the above claim(s) *8-35 and 39-68* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 36-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed August 12, 2003 has been considered. Please see the attached initialed PTO-1449. Examiner was unable to find the references lined through on the 1449. If applicants wish to furnish new copies they will, of course, be considered.

Election/Restrictions

2. Applicant's election without traverse of Group I, claims 1-7 and 36-38 in the reply filed on March 2, 2005 is acknowledged. Claims 8-35 and 39-68 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected subject matter.

The requirement is still deemed proper and is therefore made FINAL.

Priority

3. This application appears to be a division of Application No. 08/212,185, filed March 11, 1994. A later application for a distinct or independent invention, carved out of a pending application and disclosing and claiming only subject matter disclosed in an earlier or parent application is known as a divisional application or "division." The

divisional application should set forth the portion of the earlier disclosure that is germane to the invention as claimed in the divisional application. The continuity data in the specification styles this application as a continuation. In accordance with the above definition, correction is required.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-3, 5-7 36 and 38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims are directed to a receptor recognition factor where the claimed product is defined by its functional characteristics (i.e., apparent direct interaction with the ligand-bound receptor and activation of one or more transcription factors capable of binding with a specific gene). The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials."

University of California v. Eli Lilly and Co., 1997 U.S. App. LEXIS 18221, at *23, quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original).

Just as the claims at issue in *UC v. Lilly* defined the invention by the function of the claimed DNA (encoding insulin), the instant claims define the claimed products only by their functional properties. The court held this sort of functional definition insufficient. "In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly such a formula is normally an adequate description of the claimed genus. In claims to genetic material, however, a generic statement such as 'vertebrate insulin cDNA' or 'mammalian insulin cDNA,' without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is." *UC v. Lilly*, at *24-*25. Since the claimed receptor recognition factor is described only by its properties, the above claims lack adequate written description for the same reasons as the DNA in *Lilly*. The receptor recognition factor defined by claims

4 and 37 do not lack adequate written description since they define ISGF3, which is the only actual receptor recognition factor described.

Claim Rejections - 35 USC § 112, First Paragraph, Enablement

6. Claims 1-3, 5-7 36 and 38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for intact ISGF3, does not reasonably provide enablement for individual subunits of ISGF3 or other receptor recognition factors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The instant claims read on ISGF3 and any other receptor recognition factor having the claimed properties as well as reading on the subunits of ISF3 itself. The scope of the instant claims is not commensurate with the enablement of the instant disclosure, because practice of the claimed invention would require undue experimentation by an artisan of ordinary skill in the art. The lack of enablement of the individual subunits is addressed below, following the rejection for lack of utility. This rejection focuses on the lack of enablement of receptor recognition factors other than ISGF3.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some

experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

In the instant case, (1) the amount of experimentation is immense since any protein at all is a candidate to be a receptor recognition factor and each one would have to be tested to see if they have the properties recited in the claims; (2) the amount of guidance presented in the specification is zero with regard to receptor recognition factors other than ISGF3; (3) the sole working example presented is ISGF3. Continuing (4), the nature of the invention is the characterization of the receptor recognition factor known as ISGF3, involving sequencing of the subunits and determination of the function of each subunit; (5) the state of the prior art is that ISGF3 is known as are other receptor recognition factors but it is unknown whether the other receptor recognition factors have the characteristics recited in the instant claims; (6) the relative level of skill

in this art is high, that of a research scientist with a doctoral degree. The predictability of the art (7) is essentially zero since one of ordinary skill has no *a priori* knowledge of which of the myriad proteins might be an receptor recognition factor and finally, (8) the claims are quite broad since they include any protein at all, indeed, any compound at all, that has the claimed properties.

The above reasoning leads one to the inescapable conclusion that it would require undue experimentation to make and use the invention as claimed and, therefore, the claims are not enabled for their full scope.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 1-7 and 36-38 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

This rejection is based upon the premise that claims 4 and 37 claim particular subunits of ISGF3 separately, and that the other claims also read on individual subunits. For example, claim 4 says that the receptor recognition factor has an amino acid sequence selected from the group consisting of SEQ ID No.: 2, SEQ ID No.: 10 and

SEQ ID No.: 12 (emphasis added). This standard claim language means that one of the recited sequences is what is being claimed. No specific and substantial utility for the individual subunits has been disclosed and no utility is well established for each subunit.

The specification is replete with discussion of what the properties of ISGF3 are and each subunit is said to have a specific function. Each of these functions contributes to the overall activity of ISGF3 and the utility of ISGF3 as a whole is not in question; clearly, the intact receptor recognition factor can be used in the assays patented in the parent application. However, it is abundantly clear that the subunits have no utility separate from the intact receptor recognition factor. For example, the specification states that, "there is evidence that the 91 kDa protein is the tyrosine kinase target when IFNγ is the ligand." However, examiner notes that many proteins are phosphorylated by tyrosine kinase but this, in and of itself does not provide a specific and substantial utility, nor does this establish a well-known utility for the 91 kDa protein.

9. Claims 1-7 and 36-38 are also rejected under 35 U.S.C. 112, first paragraph, enablement. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-5 and 36-38 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Fu et al. (PNAS, Vol. 87, pp. 8555-8559, November 1990).

Fu et al. teach about ISGF3, its purification and identification of its constituent proteins: a DNA-binding protein of 113 kDa and three larger polypeptides (84, 91 and 113 kDa) which themselves do not have DNA binding activity. Fu et al. do not teach the sequences of the subunits, nor do they teach each and every property recited in the claims. Nevertheless, Fu et al. do teach the claimed receptor recognition factor and elucidation of such intrinsic properties as the sequence of the protein subunits and, for example, a perceived absence of interaction with G-proteins does not impart novelty upon known proteins.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fu et al. (PNAS, Vol. 87, pp. 8555-8559, November 1990).

The teachings of Fu et al. are outlined above. They do not teach labeling of ISGF3.

Labeled protein is not patentably distinct from unlabeled protein. Persons of ordinary skill in the art routinely label proteins to learn where they are in the cell, for example. Another notoriously old technique is to label antibodies in order to later detect the antibody-antigen complex during an assay. Labels that are known include horseradish peroxidase, fluorescein and radioactive isotopes and these have been used for many years as labels. It would have been obvious to one of ordinary skill in the art at the time the invention was made to label the ISGF3 of Fu et al. in order to enable further study of the protein in the cell with the reasonable, even certain, expectation of success.

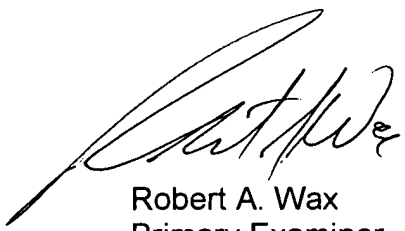
Conclusion

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Wax whose telephone number is (571) 272-0623. The examiner can normally be reached on Monday through Friday, between 9:00 AM and 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert A. Wax
Primary Examiner
Art Unit 1653

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